K113607

**Section 5: 510(k) Summary**

AUG 10 2012


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**Date Prepared:** August 8, 2012

**Classification Name:** System, X-Ray, Mammographic

**Common Name:** Mammographic X-Ray System

**Product Code:** IZH

**Proprietary Name:** Giotto Biopsy Digit S/SL

**Predicate Devices:** #K062039 Giotto Biopsy Digit AM

**Device Description:**

The Biopsy Digit S and Biopsy Digit SL are modifications to the Biopsy Digit AM needle guidance system, previously cleared as #K062039, and supplied as an accessory to the Giotto Image 3D/DL mammography system. The CMOS digital camera used on the Biopsy Digit AM is not used on the Biopsy Digit S/SL. Rather a 65mm (high) X 80mm (wide) portion of the full field amorphous selenium detector of the Giotto Image 3D/DL is used to acquire the mammographic, targeting, image data. The mechanics, cleanable surfaces, on-board electronics, and user interface software are all the same as on the biopsy Digit AM. The Biopsy Digit S/SL receives power from the Giotto Image 3D/DL. The Biopsy Digit S/SL in conjunction with the Giotto Image 3D/DL, take two exposures at separate angles ± 22.6° from the perpendicular of the digital detector centerline. The x-ray tube is driven first to one side of center and then to the other by an electro-mechanical mechanism, which is an integral part of the Giotto Image 3D/3DL, so that a stereo pair of images can be acquired. The two views provide two separate 2-dimensional projections of the subject anatomy. The two views are stored in the computer system, and can be retrieved and viewed on the computer monitor. The operator, using a mouse, identifies the region of interest on the monitor. The computer then calculates the coordinates of the region of interest in three dimensions, using trigonometry, and then transfers the coordinates to the needle-positioning unit. The software algorithm used for the calculation is identical to

that used by the Biopsy Digit AM (#K062039). The needle-positioning unit then drives the needle holder to the required location so that the operator can insert the needle or locating wire into the exact coordinates necessary.

**Intended Use:**

The Biopsy Digit S and SL are intended to be used for mammographic procedures requiring stereotactic guidance, such as fine needle aspiration, needle biopsy and guide wire placement.

**Substantial Equivalence:**

Non-Clinical testing has demonstrated that the Biopsy Digit S/SL is substantially equivalent to the predicate device, the Biopsy Digit AM. The use of new technology does not introduce new issues of safety or effectiveness.

**Discussion of Non-Clinical Testing Performed:**

Thorough non-clinical testing was performed to demonstrate that the Biopsy Digit S/SL is substantially equivalent to the predicate device, the Biopsy Digit AM, for the safe and effective use of the device for its intended use. This testing included comparative image parameter testing performed between the new aSe detector and the older CMOS detector, stereotactic accuracy testing for both biopsy systems in compliance with IEC Standard 60601-2-45, and end user validation testing of the Biopsy Digit S/SL system. In addition, testing was performed to demonstrate that the Biopsy Digit S/SL, in conjunction with the Giotto Image 3D/DL complies with the following International Standards: #60601-1, #60601-1-2, #60601-1-3, and #62304.

**Conclusions:**

The information provided in this premarket notification submission has shown that the eRAD PACS/ eRAD RIS/PACS/ eRAD EPVLite Viewer Software Product is substantially equivalent to the predicate devices and are safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Re: K113607
Trade/Device Name: Biopsy Digit S and Biopsy Digit SL
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: July 25, 2012
Received: July 26, 2012

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for use

**510(k) number (if known:**

**Device names:** Biopsy Digit S and Biopsy Digit SL

**Indications for use:** The Biopsy Digit S and SL are intended to be used for mammographic procedures requiring stereotactic guidance, such as fine needle aspiration, needle biopsy and guide wire placement.

Prescription use (Part 21 CFR 801 Subpart D) √ And/or Over-The-Counter use (Part 21 CFR 801 Subpart D) _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Radiological Devices
510k K113687